

**SURGRX**

NOV 17 2004

## 510(k) SUMMARY

### 1. Submitter Name and Address

SurgRx, Inc.  
380 Portage Avenue  
Palo Alto, CA 94306  
Contact: Linda Oleson  
Phone: (650) 739-0920 xt 107  
Date: 10/28/04

K043008

### 2. Device Name

Trade name: EnSeal Vessel Sealing & Hemostasis System (with RF-60 generator/controller)

Common name: Electrosurgical open and laparoscopic instruments and accessories

Classification name: Electrosurgical Cutting and Coagulation Device and Accessories  
(per 21 CFR section 878.4400) and Gynecologic Electrocautery and Accessories (per 21  
CFR 884.4120).

### 3. Predicate Device

EnSeal™ Vessel Sealing and Hemostasis System # K031133

### 4. Device Description

The RF-60 generator/controller which is used in conjunction with the EnSeal System.  
The functionality and remaining components of the System are the same.

### 5. Intended Use

The SurgRx EnSeal devices are intended for use during open or laparoscopic general and gynecologic surgery to cut and seal vessels, cut, grasp and dissect tissue and/or seal vessels during surgery. The SurgRx EnSeal Vessel Sealing & Hemostasis System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

### 6. Technological Characteristics

The EnSeal electrosurgical instruments are the same as the predicate devices utilizing RF powered bipolar distal ends.

### 7. Performance Data

Preclinical laboratory (bench & live animal studies) and performance tests were executed to ensure the devices function as intended and meet design specifications.

### 8. Conclusions

The EnSeal System is equivalent to the predicate devices based on results of design validation. We believe that the RF-60 generator/controller used in conjunction with the EnSeal devices is safe and effective and substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 17 2004

Ms. Linda Oleson  
Director of Clinical and Regulatory Affairs  
SurgRx, Inc.  
380 Portage Avenue  
Palo Alto, California 94306

Re: K043008

Trade/Device Name: SurgRx EnSeal Vessel Sealing & Hemostasis System

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: II

Product Code: GEI, HGI

Dated: October 29, 2004

Received: November 1, 2004

Dear Ms. Oleson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Miriam C. Provost*  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

Applicant: SurgRx, Inc.

510(k) number (if known): K 04 3008

Device Name: SurgRx EnSeal Vessel Sealing & Hemostasis System

### Indications for Use:

The SurgRx EnSeal system includes bipolar electrosurgical instruments and an accessory adapter for use with standard electrosurgical generators. It is intended for use during open or laparoscopic, general and gynecologic surgery to cut and seal vessels, cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection is performed. The devices can be used on vessels up to (and including) 7 mm and bundles as large as will fit in the jaws of the instruments.

The SurgRx EnSeal Vessel Sealing & Hemostasis System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)  
**Division of General, Restorative,  
and Neurological Devices**

Page 1 of 1

510(k) Number K 043008

13-1